May 9, 2025

Bonraybio Co., LTD.
Clare Huang
Manager
4F., No. 118, Gongye 9th Rd., Dali Dist.
Taichung, 41280
Taiwan

Re: K242388
Trade/Device Name: LensHooke X12 PRO Semen Analysis System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: POV
Dated: August 9, 2024
Received: August 12, 2024

Dear Clare Huang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 864.9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 864.9.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242388

Device Name
LensHooke X12 PRO Semen Analysis System

Indications for Use *(Describe)*
The LensHooke X12 PRO Semen Analysis System used with LensHooke Semen Test Slide is an optical device for human semen analysis which provides direct and calculated measurements for:
(1) Sperm concentration (M/mL)
(2) Total motility (PR+NP, %)
• Progressive Motility (PR, %)
(3) Sperm Morphology (normal forms, %)

The LensHooke X12 PRO Semen Analysis System used with LensHooke R10 Plus Sperm DNA Fragmentation Rapid Test Kit (SCD Assay) and LensHooke R11 Plus Sperm Double Strand DNA Fragmentation Rapid Test Kit (SDFR Assay) is an optical device for human semen analysis which provides direct measurement for:
(1) Sperm DNA Fragmentation Index (DFI, %)

The LensHooke X12 PRO Semen Analysis System does not provide a comprehensive evaluation of a male's fertility status. It is an in-vitro diagnostic system intended for human semen analysis of individuals in clinical laboratories to evaluate male fertility.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K242388

1 Submitter's Identification:

1.1 Bonraybio Co., Ltd.
4F., No.118, Gongye 9th Rd., Dali Dist., Taichung City 41280, Taiwan
Contact Person: Clare Huang
TEL: +886-4-24912385
FAX: +886-4-24912885

1.2 Date Summary Prepared: May 7th, 2025

2 Name of the device:

LensHooke X12 PRO Semen Analysis System

3 Common or Usual Name: Semen Analysis Device

Product Code	Classification	Regulation Section	Panel
POV; Semen Analysis Device	Class II	21 CFR 864.5220	Hematology 80

4 Device Description

Semen Analysis System integrates optical design and image analysis and combined with artificial intelligence image processing method, to fully automated analysis of semen quality including sperm concentration, motility, morphology and DNA fragmentation index. The images are captured and recorded by cameras and with image processing methods, the locations of sperms are detected. The sperm concentration is analyzed by the sperm unit density; the sperm motility is calculated by tracing sperm trajectories and the sperm morphology is calculated by comparing head and tail percentage. Through stained by the DNA fragmentation test kit, the DNA fragmented and non-DNA fragmented sperms is categorized and calculated the ratio number as the DNA fragmentation index.

Product Information

4.1 LensHooke X12 PRO Semen System, consist of the following devices:

LensHooke X12 PRO Semen Analysis System
LensHooke CS3 10μm Semen Test Slide
LensHooke R10 Plus Sperm DNA fragmentation Rapid Test Kit (SCD assay)
LensHooke R11 Plus Sperm Double Strand DNA Fragmentation Rapid Test Kit (SDFR assay)
LensHooke X QC Beads (For Semen)
LensHooke X QC Slide (For Semen)
Self-Test Slide

The LensHooke X12 PRO Semen Analysis System and accessories are manufactured by Bonraybio.

4.2 Accessories Description

LensHooke CS3 10μm Semen Test Slide

LensHooke Semen Test Slide is a well-designed microscopic slide for the optical analyzer, LensHooke Semen Analysis System. There are two wells and drip areas for semen sample which analyzed concentration, motility and morphology of the semen.

LensHooke X QC Beads (For Semen)

LensHooke X QC Beads is the quality control material for semen analysis. The LensHooke X QC Beads (For Semen) are supplied as three different levels of control and it has been developed as a tool to assess the accuracy and precision of sperm concentration by providing a known target value and +/- range.

LensHooke X QC Slide (For Semen)

LensHooke X QC Slide is the quality control material for semen analysis. The LensHooke X QC Slide (For Semen) are supplied as three different levels of control and it has been developed as a tool to assess the accuracy and precision of sperm concentration by providing a known target value and +/- range.

Self-Test Slide

Self-Test Slide is a standard slide form for instrument hardware check by automated detection in the analyzer.

LensHooke R10 Plus Sperm DNA Fragmentation Rapid Test Kit (SCD Assay)

LensHooke Sperm DNA Fragmentation Rapid Test Kit (SCD Assay) is an assay using Sperm Chromatin Dispersion (SCD) method for evaluating DNA fragmentation in human spermatozoa for analyzing sperm DNA fragmentation index.

LensHooke R11 Plus Sperm Double Strand DNA Fragmentation Rapid Test Kit (SDFR Assay)

LensHooke Sperm Double Strand DNA Fragmentation Rapid Test Kit (SDFR Assay) is an assay using Sperm DNA Fragmentation Release (SDFR) method for evaluating double-stranded DNA fragmentation in human spermatozoa for analyzing sperm DNA fragmentation index.

5 Indications for Use

The LensHooke X12 PRO Semen Analysis System used with LensHooke Semen Test Slide is an optical device for human semen analysis which provides direct and calculated measurements for:

(1) Sperm concentration (M/mL)

(2) Total motility (PR+NP, %)

- Progressive Motility (PR, %)

(3) Sperm Morphology (normal forms, %)

The LensHooke X12 PRO Semen Analysis System used with LensHooke R10 Plus Sperm

DNA Fragmentation Rapid Test Kit (SCD Assay) and LensHooke R11 Plus Sperm Double Strand DNA Fragmentation Rapid Test Kit (SDFR Assay) is an optical device for human semen analysis which provides direct measurement for:

(1) Sperm DNA Fragmentation Index (DFI, %)

The LensHooke X12 PRO Semen Analysis System does not provide a comprehensive evaluation of a male's fertility status. It is an in-vitro diagnostic system intended for human semen analysis of individuals in clinical laboratories to evaluate male fertility.

6 Predicate Device Information

LensHooke X12 PRO Semen Analysis System is substantially equivalent to：

LensHooke X1 PRO Semen Quality Analyzer
Device Company: Bonraybio Co., LTD.
510(k) Number: K202089

7 Comparison to Predicate Device:

Product Name	LensHooke X12 PRO Semen Analysis System (Subject Device)	LensHooke X1 PRO Semen Quality Analyzer (Predicate Device)
Intended Use	The LensHooke X12 PRO Semen Analysis System used with LensHooke Semen Test Slide is an optical device for human semen analysis which provides direct and calculated measurements for: (1) Sperm concentration (M/mL) (2) Total motility (PR+NP, %) • Progressive Motility (PR, %) (3) Sperm Morphology (normal forms, %) The LensHooke X12 PRO Semen Analysis System used with LensHooke R10 Plus Sperm DNA Fragmentation Rapid Test Kit (SCD Assay) and LensHooke R11 Plus Sperm Double Strand DNA Fragmentation Rapid Test Kit (SDFR Assay) is an optical device for human semen analysis which provides direct measurement for: (1) Sperm DNA Fragmentation Index (DFI, %) The LensHooke X12 PRO Semen Analysis System does not provide a comprehensive evaluation of a male's fertility status. It is an in-vitro diagnostic system intended for human semen analysis of individuals in clinical laboratories to evaluate male fertility.	The LensHooke X1 PRO Semen Quality Analyzer used with LensHooke Semen Test Cassette is an optical device for human semen analysis which provides direct and calculated quantitative measurements for: (1) Sperm concentration (10^6 per ml) (2) Total motility (PR+NP, %) • Progressive motility (%) • Non-Progressive motility (%) (3) Sperm morphology (normal forms, %) (4) pH value The LensHooke X1 PRO Semen Quality Analyzer does not provide a comprehensive evaluation of a male’s fertility status. It is an in-vitro diagnostic system intended for human semen analysis of individuals in healthcare professional setting to evaluate male fertility.
Male Fertility Factor	Yes	Same
Technology	Desk-top unit consists of light sources, built-in video	Same

	microscopy and an internal computer containing algorithms for the assessment of semen parameters.	
Transmission interface	HDMI/USB/Ethernet	HDMI/USB
Intended User	Professional	Point-of-Care professional
Compatible Consumable	Semen Test Slide (CS3 10μm), SCD Assay (R10 Plus), SDFR Assay (R11 Plus)	Semen Test Cassette (CS0, CS1)
Control Material	X QC Beads, X QC Slide	X QC Beads, X QC Reticle

8 Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows：

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of LensHooke X12 PRO Semen Analysis System. The evaluation included repeatability, reproducibility, LoB/LoD/LoQ, linearity, interference, sample volume, operating conditions, stability and matrix study.

9 Discussion of Clinical Tests Performed

System Accuracy Study and User Performance study

The user performance study was performed to demonstrate that professional/English reading users, across educational backgrounds can easily understand and follow the labeling/user instructions to obtain accurate results while using Subject Device. X1 RPO performed by lab personnel was used as a reference method. The study results demonstrate that the user accuracy and ease of use (via participant questionnaire scoring) of Subject Device.

10 Conclusions

Results of performance evaluation of LensHooke X12 PRO Semen Analysis System demonstrate that the subject devises are substantial equivalence to the predicate device, LensHooke X1 PRO Semen Quality Analyzer.